

Acting Director/NHLI

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Spec. Asst. for Technology/OD/NHLI

Consideration of Clinical Evaluation of LVAD.

This memo is sent for your thoughtful consideration in view of (1) the charge to me to review technological developments in NHLI, (2) the charge to me to act as coordinator of such developments in NHLI, and (3) the phenomenal pressures being put upon the CDB of DHVD of NHLI by some contractors.

An example of the lack of effective expert guidance in the direction of work in the laboratories of contractors is that of provision of left ventricular assistance when needed after open-heart operations at the end of which the left ventricle is not yet able to assume the full burden of pumping. Protests from NHLI were ignored that utilization of implanted pumps for support of a duration of less than two weeks would impose a second major operation upon an already critically ill patient. Protests from NHLI were also ignored that a procedure such as that used by DeBakey a half-dozen years ago, using blood-bearing conduits to the outside pump, would be safer because the supporting procedure could be terminated by a trivial procedure under local anesthesia.

Over these protests, the pressures from the developers were overweening, and the NHLI submitted first to a conference on Oct. 28, 1973, limited to the implanted pumps of the concerned contractors, and more recently, in drawing up guidelines for clinical trial of the LVAD, to a shortening of the period of demonstrably reliable use to 2 weeks, which may be expected to leave the patient still in the critical post-operative period after his open-heart operation.

Against this background, contrast the work of Frank Spencer a decade ago, in which he used the findings of Senning and Dennis on left heart bypass with the revision that he used a vascular graft placed at the end of the open-heart operation to lead blood from the left atrium to the outside, to be pumped by a pump external to the body back through the arterial cannula used for extracorporeal perfusion. There was salvage of a patient who had displayed myocardial inadequacy after otherwise successful cardiac repair. Two further patients were salvaged by pumping from the left ventricle to the aorta for an hour while the chest had not yet been closed, just as Crafoord had done eight years earlier.*

*F.C.Spencer, Ben Elseman, J.K.Trinkle, and N.P.Rossi; Assisted circulation for cardiac failure following intracardiac surgery with cardiopulmonary bypass. J. Thor. and Cardiovasc. Surg. 49: 56, 1965.

Contrast again the recent work of Dr. Robert Litwak, who fashioned catheters of quarter-inch internal diameter and precisely fitting obturators of teflon and silicon rubber in the kitchen of the Mount Sinai Hospital of New York to permit shunting from the left atrium to the ascending aorta of flows up to 2800 ml/min. On the termination of need for such left heart bypass 42 hours after the end of the operation, insertion of the obturators left a smooth teflon surface in the atrium and in the aorta flush with the intima. This resulted in salvage of the patient, leaving the distal ends of the two catheters buried in a subcutaneous position below the right costal margin in case support should again prove necessary. The patient is home and doing nicely more than 4 months after his ordeal. This work was done in an orderly fashion in the animal laboratory with money earned by Dr. Litwak, support for the project having been denied by the National Heart Institute (NDAP, 1969).

Clearly, in the knowledge of all this, the jingoistic prodding of the contractors to pursue the very short-term use of a bulky device implanted in either the left chest* or the abdomen represents a search for application of a device rather than the orderly search for a well-considered solution for a problem.

In view of the successes of Spencer and Litwak (although there were losses also) and in view of the concern with short-term use of implanted devices which must be removed from a patient at a time when he still is far short of recovery from his initial operation, the CBB is proposing to use \$400,000 in FY 1975 and still larger amounts later to develop "Extra or paracorporeal assist devices with percutaneous leads". This does not include development of the percutaneous leads, which is another item of similar proposed cost.

From a point of view outside the active program, the following points seem clear:

- 1) Continued development of the left ventricular implantable assist device is worth while only if for the purpose of prolonged or life-long utilization, and this would have to involve either a buried power source such as Pu238, perfection of safe percutaneous leads, or a more practical means of electromagnetic delivery of power than now exists.
- 2) For the purpose of support after open-heart operations for periods of less than two weeks, the present plan of implantation of LVAD's with proven reliability no longer than that (or even twice that) which is under consideration is simply not acceptable.
- 3) The expenditure of sums proposed to refine the method devised by Litwak does not appear at all necessary.
- 4) The phrenetic urge of some contractors to proceed quickly to clinical application of a device which is inappropriate to the clinical situation is not ethically or morally correct and could lead to censure of the program and still further legislated restrictions upon studies involving human subjects.

*It was even suggested by one contractor that the left lower pulmonary lobe be resected to provide space for the device.